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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/484,340	06/07/95	SMITH L	243132000105

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EXAMINER	
TRAN, P	
ART UNIT	PAPER NUMBER
1807	14

DATE MAILED: 12/23/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/484,340	Applicant(s) SMITH ET AL.
	Examiner PAUL B. TRAN	Group Art Unit 1807

☒ Responsive to communication(s) filed on *Oct 16, 1996* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *73-117* is/are pending in the application.

Of the above, claim(s) *112-117* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *73-111* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7, 8, 12*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. The examiner acknowledges the receipt of Applicant's Election/Amendment, Paper No. 13, filed October 15, 1996. Claims 101-107 and 109-111 have been amended.

2. Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the examiner to search and examine the inventions of Groups I and II and that the inventions of Groups I and II are not independent from each other. This is not found persuasive because a search of primers or tagged oligonucleotides would not necessarily reveal the methods of making these primers, for the reason that they are classified in different classes and that primers and method of making thereof are of divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

3. In view of the Amendment, amended claims 101-107 and 109-111, which are now drawn to primers, are joined to the elected Group I. Claims 73-111 are hereby examined on the merit. Claims 112-117 are withdrawn from further consideration by the examiner.

4. Claims 76, 77, 82 and 83 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are ambiguous because while it is drawn to a tagged primer (claims 76 and 77), or to a set comprising thereof (claims 82 and 83), the primer(s) being hybridized to a template, it is also drawn further to a method of extending the primer by a polymerase. It is therefore unclear as to what final form the primer is in, a tagged primer hybridized

to a template or an extended tagged primer which is either being hybridized to (claims 76 and 82), or separated from, the template (claims 77 and 83).

5. Claims 105-107 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are ambiguous because while they depend from Claim 101, which depends from Claim 75 which is drawn to a tagged primer base-paired to a template, they also are recited a further method in which the primer is extended and is separated from the template. That is, the claims are drawn to both a tagged primer hybridized to a template and a further method of extending the primer and separating it from the template. In other words, it is unclear as to in what final form the tagged primer is being claimed.

6. Claims 109-111 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are ambiguous because while they are drawn to a tagged primer, they are also recited to a further method comprising a chain termination DNA sequencing reaction.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 73-75, 84-86, 89, 90, 101, 102 and 104 are rejected under 35 U.S.C. § 102(b) as anticipated by Draper et al. Draper et al. teaches a poly(C) sequence which is attached with a fluorescent through an amine linker (page 1775, last full paragraph; page 1776, paragraph bridging first and second columns, Fig. 1). Although not explicitly disclosed that the sequence is a primer and that it can be extended by a polymerase, it is inherent that the sequence is also a primer (e.g. priming poly(G) containing template). Draper et al. also teaches the interaction between the fluorescently tagged poly(C) with rRNA of the 30S ribosomal subunits (page 1778, second column). In this structure, the poly(C) is considered a primer and rRNA a template.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant

is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

8. Claims 76-83, 87, 88, 91-100, 103 and 105-111 are rejected under 35 U.S.C. § 103 as being unpatentable over Draper et al. in view of Sanger et al.

Draper et al. teaches a poly(C) sequence which is attached with a fluorescent through an amine linker (page 1775, last full paragraph; page 1776, paragraph bridging first and second columns, Fig. 1). Although not explicitly disclosed that the sequence is a primer and that it can be extended by a polymerase, it is inherent that the sequence is also a primer (e.g. priming poly(G) containing template). Draper et al. also teaches the interaction between the fluorescently tagged poly(C) with rRNA of the 30S ribosomal subunits (page 1778, second column). In this structure, the poly(C) is considered a primer and rRNA a template. Not taught in Draper et al. is the chain extended product of the tagged primer. Sanger et al. teaches chain extension of a radioactive primer from a template to produce products which are subjected to nucleotide sequence analysis (page 5463, "Principle of the Method" section).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to prepare a fluorescently tagged primer which is hybridized to a template and extended by a polymerase and preparing the resulting products as those drawn in the claims. At the time of the instant invention, a fluorescently tagged primer is taught in Draper et al., and chain extension of primer is taught in Sanger et al. The artisan would have been motivated to prepare the extended fluorescently tagged primers because the products of a

primer extension reaction would be useful for sequence analysis as taught by Sanger et al.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 73, 74, 78-80, 84-87 and 89-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 7 of U.S. Patent No. 5,118,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because the oligonucleotides of '802, which are tagged with a specific group of fluorescent is functionally a primer, as is drawn in the instant application.

10. Any inquiry concerning this communication or those earlier from the examiner should be directed to Paul B. Tran, Ph.D., whose telephone number is (703) 308-4040.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose phone number is (703) 308-0196.

Paper related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Paul B. Tran, Ph.D.
Art Unit 1807
12/12/96

W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800
12/21/96